

## REMARKS

Claims 1-2, 4, 6 and 9-15 are pending in the application upon entry of the claim amendments presented herein. Claims 3, 5, 7, and 8 are canceled without prejudice to Applicant's right to pursue the subject matter recited by them in one or more divisional, continuation, and/or continuation-in-part applications.

Claims 1 and 2 are amended to recite the limitations that were recited by canceled claims 3, 5 and 7-8. Claims 4, 6 and 9 are amended to correct their dependencies. Support for new claims 14-15 can be found, for example, in Example No. 1 on page 15 of the specification. No new matter is added.

As this amendment is being filed with a Request for Continued Examination, entry of the above-identified amendments and reconsideration of the application are respectfully requested.

### **Rejections Under § 102(b)**

Claims 1-2, 7-9 and 11-13 stand rejected as allegedly anticipated by U.S. Patent No. 4,956,370 to Ippen *et al.* ("Ippen"). However, Ippen is silent as to a pharmaceutical, antimycotically active nail lacquer that includes a permeation enhancer, polymeric film forming agent, volatile solvent, and plasticizer, "such that the nail lacquer, when applied to a nail, forms an adhered, waterproof film from which the optionally substituted 2-aminothiazole of formula (I) is released so as to penetrate the nail," as is now recited in independent claims 1 and 2 as amended. Ippen is completely silent as to nail lacquers, let alone nail lacquers having the recited components and properties. Moreover, the Office Action admits that Ippen does not teach the incorporation of permeation enhancer or film forming agents (Office Action, p. 7), features now recited in independent claims 1 and 2.

Because Ippen fails to disclose each and every element of the pending claims, Applicant respectfully requests that these rejections be withdrawn.

### **Rejections Under § 103(a)**

Claims I-6 and 10 are rejected as allegedly obvious over Ippen in view of U.S. Patent No. 6,224,887 to Samour (“Samour”) and/or U.S. Patent No. 6,719,986 to Wohlrab (“Wohlrab”). However, Applicant respectfully submits that a person of ordinary skill in the art would not have had any reason to modify Ippen or combine Ippen with Samour and Wohlrab to arrive at the claimed compositions and methods.

On the basis of *KSR* and the Federal Circuit and District Court cases following *KSR*, the current standard of obviousness takes into account: (1) whether there would have been a “reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed invention does;” and (2) whether the combination of elements would have yielded “predictable results” *i.e.*, whether there would have been a reasonable expectation of success. (*See e.g., PharmaStem* 491 F.3d at 1360 (“The burden falls on the patent challenger to show by clear and convincing evidence that a person of ordinary skill in the art would have had reason to attempt to make the composition or device, or carry out the claimed process, and would have had a reasonable expectation of success in doing so.”) (emphasis added, internal quotations omitted)).

First, Applicant submits that Ippen would not have provided any reason for one of ordinary skill in the art to even attempt to make the claimed nail lacquer. Ippen discloses compositions that “may be administered locally, orally, parenterally, intraperitoneally and/or rectally, preferably parenterally, in particular intravenously,” (col. 21, lines 29-32). Ippen discloses a list more than 2 columns long of various preparations, including tablets, coated tablets, capsules, pills, granules, suppositories, solutions, suspensions and emulsions, pastes, ointments, gels, creams, lotions, powders or sprays (col. 19, line 41 to col. 21, line 68). Nothing in the list is, or even resembles, a nail lacquer. Indeed, the Office Action merely argues that Ippen’s disclosure of local administration “*for the sake of argument* ... is a sufficient teaching for one of ordinary skill in the art to clearly envisage with sufficient specificity a nail lacquer,” and that Ippen discloses that the composition can be used to treat “either dermatomycoses or systemic mycoses...which includes nails” (Office Action, p. 12) (emphasis added).

First, it is unclear to Applicants how a rejection under 35 U.S.C. §103 can stand where what the primary reference teaches should be assumed “for the sake of argument.” Regardless, the Office Action proffers no substantiating evidence that one of ordinary skill in the art given Ippen’s teaching of local, oral, parenteral, intraperitoneal and/or rectal administration, would have been prompted to create a nail lacquer, much less a nail lacquer having the components and characteristics recited in claim 1 or claim 2, “for the sake of argument” or for any other reason. As such, Applicant respectfully submits that the Office Action fails to establish a *prima facie* case of obviousness on this ground alone.

Samour and Wohlrab do not cure the deficiencies of Ippen. These references are cited as allegedly disclosing, for example, permeation enhancing agents and/or polymeric film-forming agents (Office Action, pp. 7 and 9). However, because Ippen is silent on nail lacquers generally, let alone nail lacquers having the components and properties specifically recited in claims 1 and 2, one of ordinary skill in the art would have had no reason to look to Samour and Wohlrab for additional nail lacquer components. The Office Action states that “the clear disclosure of instant invention by Ippen et al. constitutes a rational (sic) to combine Samour et al, which teach an antifungal nail lacquer” (Office Action, p. 12). Applicant respectfully submits that because Ippen’s disclosure of nail lacquers cannot reasonably be construed as “clear,” such a disclosure cannot serve as a motivation to combine Ippen with the other cited references.

Moreover, even if one of ordinary skill in the art were for some reason motivated to combine Ippen, Samour and Wohlrab, the combined teaching of these three references still falls far short of rendering obvious the claimed nail lacquer formulation, which specifically contains a permeation enhancer, polymeric film-forming agent, volatile solvent, and plasticizer, such that the nail lacquer, when applied to a nail, forms an adhered, waterproof film from which a 2-aminothiazole is released so as to penetrate the nail. The references cited by the Examiner, when considered as a whole, simply fails to teach or suggest that the claimed nail lacquer formulation, having the specific ingredients recited by claims 1 and 2, would exhibit properties recited by claims 1 and 2.

In addition, no reasonable expectation of success would have been provided by these references with regard to the claimed nail lacquer formulation. In this regard, the only

demonstration of activity that Ippen provides is an *in vitro* test carried out by plating out and incubating inocula of microorganisms with the fungicides in a nutrient medium (col. 130, lines 20-41). Even assuming that the results presented in columns 130-144 would have taught one of ordinary skill in the art to believe the fungicides could be successfully used to reduce the numbers of microorganisms in a nutrient medium, one would not have had any reason to believe that such compounds could successfully be incorporated into a nail lacquer in such a way that, when applied to a nail, forms an adhered, waterproof film from which a 2-aminothiazole is released so as to penetrate the nail, as recited in claims 1 and 2 as amended. No teaching or suggestion is provided by Samour or Wohlrab in this regard.

In contrast, as the instant specification describes, Applicant successfully demonstrated that such a nail lacquer could be used to substantially improve the symptoms of a fungal infection within 45 days of treatment, and that it is likely to completely cure a fungal infection within 100 to 150 days after the beginning of the treatment (Specification, p. 15). Applicant respectfully submits that nothing in Ippen, Samour or Whhlrab would have led one of ordinary skill in the art to reasonably expect that the claimed nail lacquer could be successfully used to so treat fungal infections.

Finally, Applicant respectfully points out that the new claims 14-15, which recite particular permeation enhancer, film forming agent, solvent, and plasticizer (claim 14) and their particular portions in the composition (claim 15), are further nonobvious over the references cited by the Examiner because the teachings of these references do not even come close to the level of specificity recited by claims 14-15.

Thus, for at least the reasons given above, Applicant respectfully submits that the pending claims are not obvious over Ippen, alone or in view of Samour and/or Wohlrab. Applicants respectfully request these rejections be withdrawn.

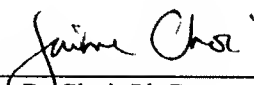
**Conclusion**

In light of the above amendments and remarks, the Applicant respectfully requests that the Examiner reconsider this application with a view towards allowance. The Examiner is invited to call the undersigned, if a telephone call could help resolve any remaining items.

An extension of time for a period of three months, the fee for which will be paid via EFS-Web, is respectfully requested. No other fees are believed due at this time. However, please charge any required fees, or credit any overpayments, to Jones Day Deposit Account No. 50-3013.

Respectfully submitted,

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